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DRINKER BIDDLE & REATH LLP  
One Logan Square  
18th and Cherry Streets  
Philadelphia, PA 19103-6996

[REDACTED] EXAMINER

FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
1654	<i>[Signature]</i>

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>10/039,666</b>	Applicant(s) <b>Purohit et al.</b>
	Examiner <b>Michele Flood</b>	Art Unit <b>1654</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1)  Responsive to communication(s) filed on Jan 29, 2003

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

#### Disposition of Claims

4)  Claim(s) 1-39 is/are pending in the application.

4a) Of the above, claim(s) 1-13 and 34-39 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 14-33 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on Jan 4, 2002 is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4

6)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restriction***

Applicant's election without traverse of Group II, claims 14-33, in Paper No. 7 is acknowledged.

Acknowledgment is made of the receipt and entry of the amendment filed on January 29, 2003.

**Claims 14-33 are under examination.**

### ***Specification***

The use of the trademark TWEEN™ has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that each letter of the trademark be capitalized or include a proper trademark symbol, such as ™ or ®.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of disinfecting water contaminated with pathogenic organisms comprising treating the contaminated water for a period ranging up to 24 hours with a composition comprising: a) an effective amount of an emulsifier selected from the Markush group recited in Claims 22-24; b) an effective amount of an essential oil; c) an effective amount of optionally an electrolyte and optionally a carrier oil selected from the Markush group of Claim 30 enabling the water to be potable comprising the exemplified wherein the pathogenic microorganisms are selected from the Markush group recited in Claim 16, does not reasonably provide enablement for a method of disinfecting water contaminated with any and all pathogenic organisms, comprising treating the contaminated water for a period ranging up to 24 hours with a composition enabling the water to be potable comprising: a) any and all emulsifiers; b) any and all essential oils; and c) optionally any and all electrolytes and optionally any and all carrier oils. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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The claims are directed to a method of disinfecting water contaminated with pathogenic microorganisms comprising treating the contaminated water for a period ranging up to 24 hours with a composition enabling the water to be potable comprising: a) an emulsifier; b) an essential oil; and c) optionally an electrolyte and optionally a carrier oil.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2D 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

The specification is non-enabling for the claim designated method as the specification does not provide guidance as to how to identify any and all emulsifiers; any and all essential oils; and any and all electrolytes and carrier oils which can be used in the making of a composition for treating water contaminated with any and all pathogenic microorganisms for a period ranging up to 24 hours to render the water potable. While it may be possible that the composition, as recited in the claims, could be useful for the claimed functional effect, it seems highly unlikely that the claimed method of water treatment could be used comprising treating water contaminated with any and all pathogenic microorganisms comprising treating the contaminated water for the claim designated time range with a composition comprising: a) any and all emulsifiers; b) any and all

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essential oils; and c) optionally any and all electrolytes and optionally any and all carrier oils to render the water potable, as broadly claimed and even after extensive experimentation.

The specification broadly discloses a method of disinfecting water contaminated with pathogenic microorganisms, e.g., *E. coli*, *Salmonella*, *Vibrio*, and *Shigella*, comprising contacting the contaminated water with the claim-designated composition for a claim-designated period of time to enable the water to be potable.

Applicant has demonstrated a method of disinfecting water contaminated with *E. coli* comprising treating the water with varying dilutions of emulsified compositions of clove oil, on pages 18-20. On page 21 (Example 8), Applicant exemplifies a composition comprising emulsified (2% TWEEN™) clove oil and different percentages of groundnut oil that is used in the claim-designated method of disinfecting water contaminated with *E. coli*. The Office notes that Applicant readily admits on page 21, lines 12-15 of the specification that the data shown in Table 13 illustrates that “in 1L volume negative results were observed for these emulsions even at 2 ml dose emulsions of E16-E20 with groundnut concentrations below 1% (Table 7) when tested in the 100 ml reaction volume yielded positive effect at the doses of 50 µl and 500 µl after 6 hrs contact period.” Applicant further exemplifies a composition comprising emulsified (2% TWEEN™) clove oil and 0.1 % saffola oil; a composition comprising emulsified (2% TWEEN™), 0.1 clove oil and 0.1 % saffola oil using varying concentrations of electrolyte solutions of either NaCl (“E22-E26”) or Na<sub>2</sub>HPO<sub>4</sub> (“E26-E29”). The Office notes that Applicant readily admits that enhanced antibacterial activity of emulsions using Na<sub>2</sub>HPO<sub>4</sub> at 0.1 and

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0.05ppm of the electrolyte was obtained than the lower concentrations. Finally, the Office notes that Applicant has demonstrated the antibacterial activity of various dilutions of hydro-alcoholic essential oils of clove oil, eucalyptus oil, and KapurTulsi oil against *E. coli*, on page 16 in Table 1; and the antibacterial activity of various dilutions of various dilutions of hydro-alcoholic essential oils of clove oil against *E. coli*, *Salmonella typhi*, and *Vibrio cholera*, on page 17 in Table 2.

While applicant has demonstrated the use of effective amounts of clove oil in combination with effective amounts of an emulsifier, namely TWEEN™; in combination with effective amounts of an optional electrolyte, namely Na<sub>2</sub>HPO<sub>4</sub> and NaCl; and, in combination with effective amounts of an optional carrier oil, namely groundnut oil and saffola oil, Applicant has not demonstrated the use of a composition comprising: a) any and all emulsifiers; b) any and all essential oils; and c) optionally any and all electrolytes and optionally any and all carrier oils to render water contaminated with any and all pathogenic microorganisms potable. There is no guidance in the specification, other than the examples directed to the application of the disclosed compositions which have the beneficial functional effect for disinfecting water contaminated with pathogenic microorganisms, such as *E. coli*, *Salmonella typhi*, and *Vibrio cholera*. The Office notes that the bactericidal efficacy of the claim-designated compositions when used in disinfecting water contaminated with pathogenic microorganisms is dependent on the concentrations, as well as the pH, of each of the recited ingredients in the claim-designated composition. It should also be noted that the state of the art at the time of filing suggests that not all essential oils have antibacterial activity. For instance, in U.S. Patent 5,153,229, Chastain et al. teach that limonene

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oil unless oxidized does not have stable antimicrobial activity (see Column 1, lines 26-60 and Column 3, lines 41-67). The state of the prior art at the time the invention was made also suggests that not all emulsifiers in combination with an essential oil would have bactericidal activity. For example, Beylier (*Perfumer & Flavorist*, 1979; 4: 23-25. *Bacteriostatic activity of some Australian essential oils*) suggests that when testing the antimicrobial activity of essential oils, one should not use cationic emulsifiers because they may present a slight bactericidal activity. Instead, Beylier advises the use of nonionic emulsifiers that have no antibacterial activity for the emulsification of essential oils for use in applications needing an antibacterial agent (see page 23, lines 24 to page 24, lines 1-35). According, it would take undue experimentation without a reasonable expectation of success to determine which amounts of the instantly claimed composition would have the claimed functional effect for disinfecting water contaminated with any and all pathogenic microorganisms to render the water potable comprising treating the contaminated water with a composition comprising: a) any and all emulsifiers; b) any and all essential oils; and c) optionally any and all electrolytes and optionally any and all carrier oils, as broadly claimed.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 20, 22-26 and 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 appears to claim a Markush group without the proper use of the Markush format. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B, and C". See *Ex parte Markush*, 1925 C. D. 126 (Comm'r Pat. 1925). Applicant may overcome the rejection by placing the word the after "from" in line 2 of Claim 16.

With regard to Claim 16, line 3, there is an apparent misspelling. Applicant may overcome the rejection by replacing "*Vibrio cholarae*" with *Vibrio cholera*.

Claim 20, line 2, is rendered vague and indefinite by the term "KapurTulsi oil". because the term is unsearchable. The examiner's preliminary analysis and extensive search demonstrates that the claimed subject matter cannot be adequately searched by class or keyword among patents and typical sources of non-patent literature.

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The metes and bounds of Claim 22 are made uncertain because the sentence lacks a period; therefore it is unclear as to whether Applicant intends for other limitations to follow the claimed subject matter.

Claims 22-24 are rendered vague and indefinite by the trademark term "Tween". The relationship between a trademark and the product it identifies is often indefinite, uncertain, and arbitrary. The formula or characteristics of the product may change from time to time and yet it may continue to be sold under the same trademark. In patent specifications, every element or ingredient of the product should be set forth in positive, exact, intelligible language, so that there will be no uncertainty as to what is meant. Arbitrary trademarks which are liable to mean different things at the pleasure of manufacturers do not constitute such language. Ex Parte Kattwinkle, 12 USPQ 11 (Bd. App. 1931). Applicant may overcome the rejection by replacing the trademark names with their corresponding chemical names.

Claim 22 is rendered vague and indefinite by the trademark terms, "Myrj" and "Bryj", for the reasons set forth immediately above. Similarly, Applicant may overcome the rejection by the trademark names with their corresponding chemical names. replacing the trademark names with their corresponding chemical names.

The metes and bounds of Claims 25, 26, 28 and 29 are rendered uncertain by the phrase "% of essential oil" because no weight or volume is associated with the phrase. The lack of clarity renders the claims ambiguous.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14, 16, 20, 21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Bose et al. (U), as evidenced by the teachings of [http://edicion-](http://edicion-micro.usal.es/web/educativo/m_especial/15btexto.2htm)  
[micro.usal.es/web/educativo/m\\_especial/15btexto.2htm](http://edicion-micro.usal.es/web/educativo/m_especial/15btexto.2htm) (V) and Rideal (W).

Applicant claims a method of disinfecting water with pathogenic microorganisms, comprising treating the contaminated water for a period ranging up to 24 hours with a composition enabling the water to be potable comprising: a) an emulsifier; b) an essential oil; and c) optionally an electrolyte and optionally a carrier oil. Applicant further claims the method as claimed in 14, wherein the contaminating pathogenic microorganisms are selected from the group consisting of *E. coli*, *Salmonella typhi* and *Vibrio cholerae*. Applicant further claims the method as claimed in claim 14, wherein the essential oil is selected from the group consisting of clove oil, eucalyptus oil and KapurTulsi oil. Applicant further claims the method as claimed in claim 20, wherein the essential oil is clove oil. Applicant further claims the method as claimed in claim 14, wherein the emulsifier is present in the composition in the range of 0.5 to 4.0% of essential oil.

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Bose teaches a method of disinfecting water with pathogenic microorganisms, comprising treating the contaminated water for a period ranging up to 24 hours with a composition enabling the water to be potable comprising a) an emulsifier; b) an essential oil; and c) optionally an electrolyte and optionally a carrier oil. For instance, on page 158, column 1, lines 10-58, Bose teaches, "0.2 c.c. of a 24-hour culture of *B. typhosus* was exposed to 5c.c. samples of the different dilutions of the disinfectant and of the phenol for varying periods at a temperature of 18°-20°C. The mixed bacilli and disinfectant water were then inoculated into broth tubes at half minute intervals. The inoculated tubes were incubated at 37°C for 48 hr. and examined for the growth." Bose also calculates the Rideal-Walker (RW.) coefficient for each of the disinfectants tested. For example, in TABLE I, Bose shows the R.W. coefficient of clove oil and eucalyptus oil in comparison to the phenol coefficient as determined by the Garrod's test. Bose further teaches that the germicidal effect of each of the essential oils against the test organism was determined by emulsifying 1% of the essential oil with 1% potassium oleate as the emulsifying agent, and 0.5% potassium carbonate as the emulsion-stabilizer. On page 158, column 2, lines 21-42, Bose teaches several essential oils having bactericidal activity, e.g., clove oil, lemongrass oil, cinnamon bark oil, palmarosa oil, ginger-grass oil, citronella oil, etc., against pathogenic microorganisms e.g., *Coli*, *Typhoid*, *Salmonella*, *Dysentery*, *Staphylococcus* groups, *Streptococcus haemolyticus*, *Pneumococcus*, and *Vibrio cholera*. See Table I on page 158 and Table III on page 159.

On page 159, column 1, lines 10-16, Bose teaches that the experimental parameters of his experiment were performed according to the Rideal-Walker test. According to <http://edicion->

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[micro.usal.es/web/educativo/m\\_especial/15btexto.2htm](http://micro.usal.es/web/educativo/m_especial/15btexto.2htm), the Rideal-Walker test entails: “Briefly, dilutions of the disinfectant are compared with standard dilutions of phenol (from 1 in 95 to 1 in 115) for their lethal activity against *Salmonella typhi* NCTC 786. To each 5 ml volume of disinfectant or phenol solution in distilled water held at 17-18°C is added 0,2ml of a 24 hour culture. At intervals 2 ½, 5, 7 ½ and 10 minutes, subcultures using a standard loop are made into Sml volumes of broth; these are then incubated for 48-72 hours at 37°C after which the presence or absence of growth in each broth is recorded.” In another example of the Rideal-Walker test, Rideal teaches similar experimental parameters for performing the Rideal-Walker test on page 461, lines 21 to page 471. According to Rideal on page 462, lines 17-22, as set forth in the teachings of Bose on page 158, column 1, lines 21-27, the Rideal-Walker coefficient is determined as follows: “The strength or efficiency of the disinfectant is expressed in multiples of carbolic acid performing the same work as the standard carbolic acid dilution, the former is divided by the latter, and a ratio termed the ‘carbolic acid co-efficient’ is thus found.” However, note that Bose teaches that in his experiment, “The Rideal-Walker coefficient was calculated by dividing the degree of dilution of the disinfectant which shows life up to 5 min. but no life thereafter, by that figure indicating the degree of the corresponding dilution of phenol.” Thus, the RW coefficients of the essential oils calculated by Bose in Table I represent the “killing action” of the emulsified essential oils against various pathogenic microorganism organisms in distilled water, as well as against *B. typhosus* (renamed *Salmonella typhosus*) in the presence of different kinds of organic matter. See page 159, lines 40-46.

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The reference anticipates the claimed subject matter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-19, 25, 26, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Nitsas (N) in view of Rideal (W).

Applicant's claimed invention of Claims 14, 16 and 25 was set forth above. Applicant further claims the method of claim 14, wherein the contaminated water is treated for a period of between 6-8 hours. Applicant further claims the method as claimed in claim 14, wherein the amount of composition used for disinfecting the pathogen contaminated water is in the ratio of about 1:100000 to 1:200000 of composition to water. Applicant further claims the method claimed in claim 17, wherein the amount of composition used for disinfecting the pathogen contaminated water is in the ratio of about 1:10000 to 1:20000 of composition to water.

Applicant further claims the method as claimed in claim 14, wherein the amount of composition used for disinfecting the pathogen contaminated water is in the ratio of about 1:20000 to 1:200000 of composition to water. Applicant further claims the method as claimed in claim 25, wherein the emulsifier is present in the composition in the range of about 1.5 to 3.0% of essential

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oil. Applicant further claims the method as claimed in claim 14, wherein the essential oil comprises a hydro-alcoholic preparation of essential oil. Applicant further claims the method as claimed in claim 31, wherein the ratio of contaminated water to hydro-alcoholic solution of essential oil is in the range between 10:1 to 5000:1.

On page 10, lines 12-19 and lines 28-31, Nitsas teaches a composition comprising a hydro-alcoholic preparation of the essential oil of *Origanum hyrtum* (5%), EMULGATOR 484™ (3%, an anionic alkylphenol ethoxylated emulsifier), propylene glycol (10% emulsifier), and distilled water (82%), which is used a method of disinfecting drinking water. For instance, Nitsas teaches on page 7, lines 17-25, “Accordingly, in a preferred embodiment of the present invention, the pharmaceutical composition is used for the purification of water. In a concentration of about 10 to 20 ml of a 5% aqueous solution of the essential oil per cubic meter water, the ingredients of the essential oils according to the present invention provide a bacteriostatic effect without impairing the odour and taste of drinking water. See page 5, lines 13-15, wherein a method of preparing the referenced plant extract is taught. Nitsas further teaches that the hydro-alcoholic preparation of the essential oil of *Origanum hyrtum* is effective in treating disease conditions caused by *Salmonella* and *Escherichia coli*. See also, claims 1-5 and 10.

The teachings of Nitsas are set forth above. Nitsas teaches the claimed invention except for the instantly claimed period of treatment of the contaminated water, the instantly claimed ratios for the amount of composition used for disinfecting the pathogen to the contaminated water, and the instantly claimed ratio of contaminated water to hydro-alcoholic solution of

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essential oil. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the method of disinfecting water contaminated with pathogenic microorganisms taught by Nitsas by incorporating the instantly claimed experimental parameters because Rideal teaches a method of determining the bactericidal efficacy of a disinfectant against pathogenic organisms in a water medium. For instance, on page 461, lines 21-30 to page 471, Rideal teaches several factors to determine the efficacy of a disinfectant, which encompass 1) Time; 2) Age of culture; 3) Choice of Medium. Reaction of same; 4) Temperature of Incubation; 5) Temperature of Medication; 6) Variations vital resistance of same species; 7) Variations in vital resistance of different species; 8) Proportion of culture to disinfectant. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to optimize the method of disinfecting water contaminated with pathogenic microorganisms taught by Nitsas by incorporating the instantly claimed experimental parameters because Rideal teaches the means and importance of determining the bactericidal efficacy of a disinfectant in a water medium against pathogenic organisms, e.g., *Salmonella typhosus*, relative to the time period of treatment of the contaminated water with regard to the dilution of the sample disinfectant, as set forth on page 463 to 465, in Tables II, II<sub>A</sub>, III, III<sub>A</sub> and III<sub>B</sub> and corresponding text; and relative to the ratios of composition(i.e., hydro-alcoholic solution of essential oil) to water, as well as, relative to the ratio of contaminated water to hydro-alcoholic solution of essential oil, as set forth on page 470, under '8<sup>th</sup>. *Proportion of culture to disinfectant*', and Tables IX and IX<sub>A</sub>. Thus, the effective varying of

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the period of time, the ratio for the amounts of the composition used for disinfecting the pathogen contaminated water, and the ratio of contaminated water to the hydro-alcoholic solution of essential oil taught by Nitsas would have been no more than a routine matter of optimization for one of ordinary skill in the art at the time the invention was made, especially since Nitsas teaches the bactericidal activity of the referenced composition comprising an emulsified hydro-alcoholic essential oil of *Origanum hyrtum* against various pathogenic microorganisms in a concentration of about 10 to 20 ml of a 5% aqueous solution of the essential oil per cubic meter water, and that the referenced hydro-alcoholic essential oil has bactericidal and bacteriostatic in high dilutions (see page 7, lines 11-15). Moreover, references in conventional result-effective work conditions (e.g., ingredient concentrations) do not support the patentability of claimed subject matter, unless there is clear and sufficient evidence indicating such working condition(s) is/are critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation" (see, e.g., MPEP 2144.05).

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed method are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

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Claims 14 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emerson et al. (A) in view of Lawless (X) and Beylier et al. (U1).

Applicant's claimed invention of Claim 14 as set forth above. Applicant further claims the method as claimed in claim 14, wherein the emulsifier is selected from a recited Markush group. Applicant further claims a method as claimed in claim 23, wherein the emulsifier comprises a TWEEN™ surfactant. Applicant further claims the method as claimed in claim 23, wherein the emulsifier comprises TWEEN 20™.

Emerson teaches a method of disinfecting water contaminated with pathogenic organisms comprising treating the contaminated water with aromatic aldehydes or alcohols for a period of time sufficient to enable the water potable. The aromatic aldehydes or alcohols useful in the method of water treatment taught by Emerson include benzaldehyde, acetaldehyde, cinnamaldehyde, piperonal and vanillin, which kill or inhibit the growth of pathogenic organisms, e.g., *Salmonella*, *B. subtilis*, *B. megaterium*, *C. botulinum*, protozoa such as *Giardia*, viruses and algae (see Column 2, line 12 to Column 3, lines 1-13 and Column 5, line 62 to Column 6, lines 1-13). In Column 3, lines 60-65, Emerson teaches using 0.01 and 5.0 weight percent, preferably between 0.1 and 2.5 weight percent of the aromatic aldehyde or alcohol in formulating the effective microbial-inhibiting compositions in the referenced method. In Column 3, lines 37-42, Emerson teaches that the compositions include an emulsifier, i.e., TWEEN-80™; and, that the composition optionally comprises an electrolyte: "These aqueous composition optionally

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contain a salt of a polyprotic acid such as sodium bicarbonate, sodium sulfate, sodium phosphate or sodium biphosphate.”

The teachings of Emerson are set forth above. Emerson teaches the claimed method of disinfecting water contaminated with pathogenic organisms for an essential oil, wherein the period of water treatment ranges up to 24 hours, and wherein the emulsifier comprises TWEEN-20™. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the ingredients used in the method of water treatment taught by Emerson with the instantly claimed ingredients because Lawless teaches essential oils comprising aromatic aldehydes or alcohol compounds and Beylier teaches that incorporating TWEEN™ as an emulsifier in the making of antibacterial emulsions of essential oils provides for a stable product. Firstly, on page 206, Lawless teaches under ‘PRINCIPLE CONSTITUENTS’ that the essential oil of *Prunus dulcis* (almond oil) comprises benzaldehyde (95%). On page 113, Lawless teaches under ‘PRINCIPLE CONSTITUENTS’ that the essential oil of the leaf of *Cinnamomum zeylanicum* (cinnamon oil) comprises cinnamaldehyde (3%) and that the essential oil of the bark of *Cinnamomum zeylanicum* comprises cinnamaldehyde (40-50%) and benzaldehyde. Lawless further teaches that the essential oil of cinnamon has antimicrobial and antiseptic activities. On page 112, Lawless teaches under ‘PRINCIPLE CONSTITUENTS’ that the essential oil of both leaf and bark of *Cinnamomum cassia* comprises cinnamic aldehyde (75-90%). Finally, on page 233, Lawless teaches under ‘PRINCIPLE CONSTITUENTS’ that the essential oil of *Vanilla planifolia* (vanilla bean/pod oil) comprises vanillin (1.3-2.9%) and hydroxybenzaldehyde. At the

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time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add and/or replace the aromatic aldehydes or alcohol with an essential oil to provide the claimed invention because Lawless teaches essential oils comprising the aromatic aldehydes of alcohols taught by Emerson, which have antimicrobial activity, and/or are used in the food processing industry as flavorants. Secondly, Beylier teaches a method of testing the bactericidal activity of an essential oil which gives the best and most reproducible results and method of making a product comprising an essential oil, which provides reproducible results of bactericidal activity by emulsifying the essential oil. On page 23, column 2, lines 18-28, Beylier teaches, "Only Tween 20 and Tween 80, when tested alone, have no antibacterial activities. The best antibacterial activities are obtained with mixtures of Tween 20 and oil in a proportion of 10 to 50 or 20 to 80. If greater quantities of Tween are used, the antibacterial power decreases. The chemical stability of the mixture emulsifier and oil is demonstrated by the fact that chromatograms of pure oil and oil mixed with emulsifier after a period of six months are absolutely the same." One of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to replace the aromatic compounds taught by Emerson with the instantly claimed essential oils and to replace the TWEEN-80<sup>TM</sup> taught by Emerson with the instantly claimed TWEEN-20<sup>TM</sup> to provide the claimed invention because at the time the invention was made Lawless taught essential oils having antimicrobial and antiseptic activities comprising the aromatic aldehydes or alcohol compounds taught by Emerson and Beylier taught that TWEEN-20<sup>TM</sup> is the best emulsifier of essential oils

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because it exhibits no antibacterial activity when tested alone, is chemically stable, and provides a shelf-stable product. Thus, the instantly claimed limitations are no more than a substitution of known ingredients, one for the other, in the making of a composition that is used for disinfecting water contaminated with pathogenic microorganisms enabling the water to be potable. Hence, one of ordinary skill in the art would have been motivated and had a high expectation of success to substitute one ingredient for the other because the prior art references suggest that the instantly claimed ingredients are no more than functional equivalents of the referenced ingredients.

With regard to the claimed limitation of Claim 14 wherein Applicant claims "treating the contaminated water for a period ranging up to 24 hours with a composition enabling the water to be potable, it would have been well in the purview of one of ordinary skill in the art to optimize the teachings of Emerson to provide the instantly claimed limitation because Emerson teaches in Column 6, lines 64-67 to Column 7, lines 1-19 and Column 7, lines 60-67 to Column 8, lines 1-6, a method for determining the optimal dose-ranges for formulating compositions that incorporate the referenced biocidal ingredients to decontaminate an environment and a method for determining the concentrations of a formulation comprising the referenced biocidal ingredients that is needed to inhibit organism growth for a measured length of time.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

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Claims 14-19, 25-29, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Nitsas (N) and Rideal (W) in view of Benn et al. (D).

Applicant's claimed invention of Claims 14-19, 25, 26, 32 and 33 was set forth above. Applicant further claims the method as claimed in claim 14, wherein the carrier oil comprises an unsaturated vegetable oil. Applicant further claims the method as claimed in 14, wherein the carrier oil is present in the composition in the range of about 0.01 to 5.0 % of essential oil. Applicant further claims the method in claim 28, wherein the carrier oil is present in the composition in the range of about 0.01 % to 0.5 % of essential oil.

The combined teachings of Nitsas and Rideal are set forth above. The combined teachings of Nitsas and Rideal teach the claimed invention except for wherein the carrier oil comprises an unsaturated vegetable oil and wherein the vegetable oil is present in the instantly claimed ratios of carrier oil to essential oil. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition used in the method of water treatment taught by the combined teachings of Nitsas and Rideal by adding vegetable oil as a carrier oil to provide the claimed invention because Benn teaches a method for treating drinking water comprising adding hydrophobic oil droplets, e.g., vegetable, olive oil, soybean oil, coconut oil and rapeseed oil, to contaminated waters to remove dissolved and particulate contaminates (wherein the size range of the contaminant ranges 10-7 to 10-2 cm in diameter; see Column 1, lines 36-43) in water treatment systems, in Column 2, lines 5-21. In Column 2, lines 50-61, Benn teaches, "The quantity of oil added to the water is about the same as or less than the quantity of

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contaminant in the water." In Column 5, lines 5 to Column 6, lines 1-25, Benn teaches, "Addition of water-soluble surfactants, such as those used in soaps allows stabilization of these small droplets and possible capture of small contaminants." In Column 6, lines 37-67, Benn further teaches the addition of water soluble salts to overcome the repulsive forces between colloidal particles. At the time the invention was made, one of ordinary skill in the art would have been motivated and one of ordinary skill in the art would have had a reasonable expectation of success to add a vegetable oil as a carrier oil to the composition used in the method of water treatment taught by the combined teachings of Nitsas and Rideal because Benn suggests that the addition of vegetable oils to water treatment systems may remove biologically active pathogenic material, in Column 8, lines 28-52 As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed method are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed method are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

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Claims 14 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Nitsas (N) and Rideal (W) in view of Kurita et al. (V1), Jovanvic (O), Hamernik (P), Eibl et al. (C) and Baldelli (Q).

Applicant's claimed invention of Claim 14 was set forth above. Applicant further claims the method as claimed in claim 14, wherein the electrolyte is NaCl or Na<sub>2</sub>HPO<sub>4</sub>. Applicant further claims the method as claimed in claim 14, wherein the electrolyte is present in the composition in the range between 0.01 to 0.1 ppm of essential oil.

The combined teachings of Nitas and Rideal was set forth above. The combined teachings of Nitas and Rideal teach the claimed invention except for The combined teachings of Emerson, Lawless and Baylier teach the claimed invention except for wherein the electrolyte is NaCl or Na<sub>2</sub>HPO<sub>4</sub>, and wherein the electrolyte is present in the composition in the range between 0.01 to 0.1 ppm of essential oil. However, it would have been obvious to one of ordinary skill in the art to substitute the electrolytes, i.e., sodium bicarbonate, sodium sulfate, sodium phosphate or sodium biphosphate, used in the making of the composition for the method of disinfecting water contaminated with pathogenic microorganisms taught by the combined teachings of the prior art references because at the time the invention was made it was well known in the art to add to use the instantly claimed electrolytes in a method of disinfecting water to enable the contaminated water to be potable, as evidenced by the teachings of Kurita, Hamernik, Eibl, Baldelli and Javonvic. Firstly, Kurita teaches the antimicrobial effect of a variety of essential oil components against fungi in the presence of various concentrations of NaCl. For instance, Kurita

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teaches that in the presence of 7 to 10% NaCl , cinnamaldehyde, perillaldehyde, citral, citronellol, perillalcohol, geraniol, cuminaldehyde and eugenol exhibited potent antimicrobial effect at a concentration of less than 1nM. Moreover, each of the references of Hamernik, Eibl, Baldelli teach methods of adding solutions of NaCl to waters contaminated with pathogenic microorganisms to render the waters potable. Secondly, Javonvic teaches purifying drinking water or clarifying waste-waters by adding a 14% solution of di:sodium hydrogen phosphate ( $\text{Na}_2\text{HPO}_4$ ) and optionally an aqueous calcium ion-containing solution (4%) to the waters to be treated. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the instantly claimed electrolytes to the method of water treatment taught by the combined teachings of Nitas and Rideal to provide the claimed invention because Kurita teaches that a variety of plant essential oils exhibit a potent synergistic antimicrobial effect with NaCl, which suggests that a combination of plants high in essential content are applicable in place of synthetic preservatives or antimicrobials in food products; furthermore, the teachings of Hamernik, Eibl, Baldelli and Javonvic indicate that the disinfection of waters contaminated with pathogenic organisms by the addition of amounts of NaCl to enable the water to be potable was well known and routine in the art at the time the invention was made; and, Jovanvic teaches that the addition of a solution of  $\text{Na}_2\text{HPO}_4$  and optionally a calcium ion-containing solution in a method of drinking or waste-water purification reduces the cost of purifying water and clarifying waters, dissolves and precipitates heavy metal compounds from treated waters, and reduces water hardness.

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As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed method are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 14, 22-24 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emerson et al. (A), Lawless (X) and Beylier et al. (U1) in view of Kurita et al. (V1), Jovanovic (O), Hamernik (P), Eibl et al. (C) and Baldelli (Q).

Applicant's claimed invention of Claims 14 and 22-24 was set forth above. Applicant further claims the method as claimed in claim 14, wherein the electrolyte is NaCl or Na<sub>2</sub>HPO<sub>4</sub>. Applicant further claims the method as claimed in claim 14, wherein the electrolyte is present in the composition in the range between 0.01 to 0.1 ppm of essential oil.

The combined teachings of Emerson, Lawless and Baylier was set forth above. The combined teachings of Emerson, Lawless and Baylier teach the claimed invention except for wherein the electrolyte is NaCl or Na<sub>2</sub>HPO<sub>4</sub>, and wherein the electrolyte is present in the composition in the range between 0.01 to 0.1 ppm of essential oil. However, it would have been obvious to one of ordinary skill in the art to substitute the electrolytes, i.e., sodium bicarbonate, sodium sulfate, sodium phosphate or sodium biphosphate, used in the making of the composition

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for the method of disinfecting water contaminated with pathogenic microorganisms taught by the combined teachings of the prior art references because at the time the invention was made it was well known in the art to add to use the instantly claimed electrolytes in a method of disinfecting water to enable the contaminated water to be potable, as evidenced by the teachings of Kurita, Hamernik, Eibl, Baldelli and Javonvic. Firstly, Kurita teaches the antimicrobial effect of a variety of essential oil components against fungi in the presence of various concentrations of NaCl. For instance, Kurita teaches that in the presence of 7 to 10% NaCl , cinnamaldehyde, perillaldehyde, citral, citronellol, perillalcohol, geraniol, cuminaldehyde and eugenol exhibited potent antimicrobial effect at a concentration of less than 1nM. Moreover, each of the references of Hamernik, Eibl, Baldelli teach methods of adding solutions of NaCl to waters contaminated with pathogenic microorganisms to render the waters potable. Secondly, Javonvic teaches purifying drinking water or clarifying waste-waters by adding a 14% solution of di:sodium hydrogen phosphate ( $\text{Na}_2\text{HPO}_4$ ) and optionally an aqueous calcium ion-containing solution (4%) to the waters to be treated. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the instantly claimed electrolytes to the method of water treatment taught by the combined teachings of Emerson, Lawless and Baylier to provide the claimed invention because Kurita teaches that a variety of plant essential oils exhibit a potent synergistic antimicrobial effect with NaCl, which suggests that a combination of plants high in essential content are applicable in place of synthetic preservatives or antimicrobials in food products; furthermore, the teachings of Hamernik, Eibl,

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Baldelli and Javonvic indicate that the disinfection of waters contaminated with pathogenic organisms by the addition of amounts of NaCl to enable the water to be potable was well known and routine in the art at the time the invention was made; and, Jovanvic teaches that the addition of a solution of  $\text{Na}_2\text{HPO}_4$  and optionally a calcium ion-containing solution in a method of drinking or waste-water purification reduces the cost of purifying water and clarifying waters, dissolves and precipitates heavy metal compounds from treated waters, and reduces water hardness.

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed method are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

*Michele C. Flood*  
MICHELE FLOOD  
PATENT EXAMINER

MCF  
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